AMENDMENTS TO THE CLAIMS

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A stable topical nanoparticulate spironolactone formulation comprising nanoparticles of spironolactone ~~having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 300 nm to about 900 nm,~~ incorporated into a crystalline network ~~system comprising a dispersion of solid crystals~~ of polar lipids, wherein the nanoparticles of spironolactone have a mean diameter measured by photon correlation spectroscopy in the range of from about 300 nm to about 900 nm.

~~said lipids exposing their hydrophilic side outwards and their hydrophobic side inwards toward the spironolactone nanoparticles~~.

2. (Previously Presented) The formulation according to claim 1, comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 400 nm to about 600 nm

3. (Previously Presented) The formulation according to claim 1, wherein the lipid has a crystallization temperature of between 20°C and 100°C.

4. (Currently Amended) The formulation according to claim 1, wherein the ~~lipid crystals are~~crystalline network of polar lipids is formed from β crystals of a monoglyceride of a fatty acid having 12-18 carbon atoms, or ascorbic, phosphate or lactic esters of fatty acids or of monoglycerol ethers, or mixtures thereof.

5. (Previously Presented) The formulation according to claim 4, wherein the monoglyceride is 1-monolaurin, 1-monomyristin, 1-monopalmitin, or 1-monostearin, or a mixture of two or more thereof.

6. (Previously Presented) The formulation according to claim 1, wherein crystalline network structures of polar lipids are formed within a polar liquid.

7. (Previously Presented) The formulation according to claim 6, wherein the polar liquid is selected from water, glycerol, ethylene glycol, propylene glycol, or mixtures thereof.

8. (Previously Presented) A method of treating one or more of acne, hirsutism, androgenic alopecia, or rosacea, comprising topically applying to a subject in need thereof the nanoparticulate spironolactone formulation according to claim 1.

9. (Previously Presented) The formulation according to claim 1, wherein active drug is incorporated in the form of a nanosuspension.

10. (Previously Presented) The formulation according to claim 9, wherein the nanosuspension is an aqueous nanosuspension.

11. (Previously Presented) The formulation according to claim 10, wherein the nanosuspension comprises a stabilizer.

12. (Previously Presented) The formulation according to claim 11, wherein the stabilizer is sodium docusate.

13.-17. (Cancelled)

18. (Previously Presented) A method of treating a condition that responds to anti-androgens comprising: administering a stable nanoparticulate spironolactone formulation according to claim 1 to a patient in need of such treatment, wherein said condition is acne, hirsutism, androgenic alopecia, or rosacea.

19. (Cancelled)

20. (Cancelled)

21. (Currently Amended) A process for the preparation of a stable topical nanoparticulate spironolactone formulation ~~comprising nanoparticles having a mean diameter in the range of from about 300 nm to about 900 nm as measured by photon correlation spectroscopy, said process~~ comprising: ~~incorporating a nanosuspension of~~ dispersing nanoparticulate spironolactone into a mixture of polar lipids and a polar liquid at a temperature below the transition temperature of the lipid but above the temperature at which the lipid crystalline structure is fully formed.~~an aqueous dispersion of solid crystals of polar~~

~~lipids, said lipids having their hydrophilic side exposed outwards and their hydrophobic side inwards toward the spironolactone nanoparticles.~~

22. (Currently Amended) A method of treating a condition that responds to anti-androgens, comprising administering a stable topical nanoparticulate spironolactone ~~nanosuspension~~ formulation comprising nanoparticles of spironolactone incorporated into a crystalline network of polar lipids ~~having a mean diameter in the range of from about 300 nm to about 900 nm, as measured by photon correlation spectroscopy,~~ in an amount effective to treat the condition, wherein said condition is acne, hirsutism, androgenic alopecia, or rosacea, and wherein the nanoparticles of spironolactone have a mean diameter measured by photon correlation spectroscopy in the range of from about 300 nm to about 900 nm..

23. (Previously Presented) The method according to claim 8, wherein spironolactone active drug is incorporated into the formulation in the form of a nanosuspension.

24. (Previously Presented) The method according to claim 18, wherein spironolactone active drug is incorporated into the formulation in the form of a nanosuspension.

25. (Previously Presented) The formulation according to claim 1, wherein said nanoparticles do not grow following seven months in storage at room temperature.

26. (Previously Presented) The method according to claim 21, wherein said nanoparticles do not grow following seven months in storage at room temperature.

27. (Previously Presented) The method according to claim 22, wherein said nanoparticles do not grow following seven months in storage at room temperature.